(2) *Codeine ingredients.* The following ingredients may be used only in combination in accordance with §§ 290.2 and 21 CFR 1308.15(c).
(i) Codeine.
(ii) Codeine phosphate.
(iii) Codeine sulfate.
(3) Dextromethorphan.
(4) Dextromethorphan hydrobromide.
(5) Diphenhydramine citrate.
(6) Diphenhydramine hydrochloride.
(b) *Topical antitussives.*
(1) Camphor.
(2) Menthol.

[52 FR 30055, Aug. 12, 1987, as amended at 59 FR 29174, June 3, 1994; 67 FR 4907, Feb. 1, 2002]

§ 341.16 Bronchodilator active ingredients.

The active ingredients of the product consist of any of the following when used within the dosage limits established for each ingredient:
(a) Ephedrine.
(b) Ephedrine hydrochloride.
(c) Ephedrine sulfate.
(d) Epinephrine.
(e) Epinephrine bitartrate.
(f) Racephedrine hydrochloride.
(g) Racepinephrine hydrochloride.

[51 FR 35339, Oct. 2, 1986]

§ 341.18 Expectorant active ingredient.

The active ingredient of the product is guaifenesin when used within the dosage limits established in § 341.78(d).

[54 FR 8509, Feb. 28, 1989]

§ 341.20 Nasal decongestant active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage forms established for each ingredient:
(a) *Oral nasal decongestants.* (1) Phenylephrine hydrochloride.
(2) Pseudoephedrine hydrochloride.
(3) Pseudoephedrine sulfate.
(b) *Topical nasal decongestants.* (1) Levmetamfetamine.
(2) Ephedrine.
(3) Ephedrine hydrochloride.
(4) Ephedrine sulfate.
(5) [Reserved]
(6) Naphazoline hydrochloride.
(7) Oxymetazoline hydrochloride.
(8) Phenylephrine hydrochloride.
(9) Propylhexedrine.
(10) Xylometazoline hydrochloride.

[59 FR 43409, Aug. 23, 1994, as amended at 63 FR 40650, July 30, 1998]

Subpart C—Labeling

§ 341.40 Permitted combinations of active ingredients.

The following combinations are permitted provided each active ingredient is present within the dosage limits established in parts 341, 343, and 356 of this chapter and the product is labeled in accordance with §§ 341.70 or 341.85:

(a) Any single antihistamine active ingredient identified in § 341.12 may be combined with any generally recognized as safe and effective single analgesic-antipyretic active ingredient, or any combination of acetaminophen with other analgesic-antipyretic active ingredients, or any aspirin and antacid combination provided that the product is labeled according to § 341.85.

(b) Any single antihistamine active ingredient identified in § 341.12 may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a) provided that the product is labeled according to § 341.85.

(c) Any single antihistamine active ingredient identified in § 341.12 may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a) and any generally recognized as safe and effective single analgesic-antipyretic active ingredient, or any combination of acetaminophen with other analgesic-antipyretic active ingredients, or any aspirin and antacid combination provided that the product is labeled according to § 341.85.

(d) Any single antihistamine active ingredient identified in § 341.12(a) through (e) and (h) through (m) may be combined with any single oral antitussive active ingredient identified in § 341.14(a)(1) through (a)(4) provided that the product is labeled according to § 341.85(c)(4). Diphenhydramine citrate in §§ 341.12(f) and 341.14(a)(5) or diphenhydramine hydrochloride in §§ 341.12(g) and 341.14(a)(6) may be both the antihistamine and the antitussive active ingredient provided that the product is labeled according to § 341.70(a).